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JANSSON, SHUPE, MUNGER & ANTARAMIAN, LTD
245 MAIN STREET
RACINE, WI 53403

EXAMINER
KRAMER, NICOLE R

ART UNIT	PAPER NUMBER
3762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

C

Office Action Summary	Application No. 10/781,427	Applicant(s) ZIOBRO ET AL.
	Examiner Nicole R. Kramer	**Art Unit** 3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 26 April 2006.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 46-68 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 46-68 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 65-66 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication 2004/0158298 ("Gliner et al.").

With respect to claim 65, Examiner notes that applicant has invoked 112, 6th paragraph. Examiner considers the means disclosed in Gliner et al. to be equivalent to the means disclosed in the present application. More particularly, Gliner discloses equivalent means for stimulating a portion of a cortex (electrode array 110 operatively connected to a pulse system 140 for generating and sending energy pulses to the electrode array as described in paragraph 0024); equivalent means for detecting a muscle reaction to the stimulating (sensing unit 180 may be an electromyograph for detecting reaction to the stimulating; see, for example, paragraphs 0033-0034); equivalent means for associating the detecting with the stimulating (a controller 130 which sends command signals to the pulse system 140 defining the configuration of

active electrodes and waveform parameters for the stimulus, and receives signals corresponding to the magnitude of the responses from the sensing device 180 as described in paragraph 0027. The controller associates the reaction with one of the individual pairs of the plurality of subdural electrodes in that the controller performs an evaluation procedure 240 and analyzing procedure 260 which utilizes sensed peripheral responses from the EMG sensors in order to determine an optimal electrode configuration and/or stimulus parameters; see, for example, paragraphs 0032 - 0036); and equivalent means for notifying a user of the mapped functional identification in relation to discrete cortical locations being stimulation (the optimization process can terminate by displaying the optimized electrode configuration to a practitioner, or otherwise presenting the optimized electrode configuration for use; see paragraph 0044). Examiner considers "producing a map identifying at least one specific functional location of the cortex" to encompass the associating step disclosed in Gliner et al. because Gliner et al. necessarily establishes a functional relationship between the applied stimulus location and the detected EMG event (i.e., that the applied stimulus resulted in a the particular detected muscle reaction).

With respect to claim 66, Gliner et al. discloses a method comprising utilizing individual electrodes pairs of a grid of subdural electrodes (electrode array 110 as described above) as selectable stimulus points (stimulus unit 120 includes a pulse system 140 for generating and sending energy pulses to selectable electrodes of electrode array as described in paragraph 0024) in a closed loop system of cortical mapping based on electromyographic detection events (stimulus unit 120 includes a

controller 130 which sends command signals to the pulse system 140 defining the configuration of active electrodes and waveform parameters for the stimulus as described in paragraph 0027). The controller detects EMG events in response to the applied stimulus (controller 130 receives signals corresponding to the magnitude of the responses from the sensing device 180 as described in paragraph 0027) and associates the detected reaction with one of the individual pairs of the plurality of subdural electrodes (the controller performs an evaluation procedure 240 and analyzing procedure 260 which utilizes sensed peripheral responses from EMG sensors in order to determine an optimal electrode configuration and/or stimulus parameters; see, for example, paragraphs 0032 - 0036). Examiner considers "utilizing the detected EMG events to map the cortex" to encompass the associating step disclosed in Gliner et al. because Gliner et al. necessarily establishes a functional relationship between the applied stimulus location and the detected EMG event (i.e., that the applied stimulus resulted in a the particular detected muscle reaction).

Claim Rejections - 35 USC § 102/103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 43-48, 50-52, 54-59, and 61-64 are rejected under 35 U.S.C. 102(e) as being anticipated by, or in the alternative as being unpatentable over, U.S. Patent Application Publication 2004/0158298 ("Gliner et al.").

Gliner et al. discloses a system (system 100) and method for optimizing stimulus parameters and electrode configurations for neurostimulators. A plurality of subdural electrodes formed as a grid are installed onto the cortex of a patient (electrode array 110 can be a grid having a plurality of discreet electrodes 114 arranged in an X-Y coordinate system; see paragraph 0023. The electrode array can be a cortical neural-stimulation device in which the electrodes are placed generally over or proximate to a target location such as the surface of the cortex for stimulation; see paragraphs 0025 and 0045). A cortical stimulator is used to sequentially stimulate individual pairs of the plurality of subdural electrodes (stimulus unit 120 includes a pulse system 140 for generating and sending energy pulses to the electrode array as described in paragraph 0024. Further, the stimulus unit 120 includes a controller 130 that sends command signals to the pulse system 140 defining the configuration of active electrodes and waveform parameters for the stimulus as described in paragraph 0027. The stimulating procedure 220 involves several iterations performed by the controller in which the configuration of the electrodes and/or the stimulus parameters can be changed at each iteration; see paragraph 0032. Gliner et al. discloses various stimulation patterns in paragraphs 0046 with reference to Figures 4A-4C, including stimulating individual pairs of immediately adjacent electrodes of the grid as illustrated at Fig. 4C).
Electromyograph (EMG) sensors are utilized at predetermined muscle locations of the

patient for detecting muscle contractions in response to the applied stimulation (sensing deice 180 is operatively coupled to the stimulus unit 120; see paragraph 0022. The sensing device 180 may be an any suitable apparatus for determining a response in the patient to a stimulus applied to the electrode array as described in paragraph 0026. Gliner et al. discloses that the sensing device 180 can be an EMG device; see, for example, paragraphs 0033-0034). The controller associates or assigns the detected muscle reaction with one of the individual pairs of the plurality of subdural electrodes (controller 130 receives signals corresponding to the magnitude of the responses from the sensing device 180 as described in paragraph 0027. The controller assigns a one-to-one correspondence between the detected muscle contraction event and a particular pair of electrodes in that the controller performs an evaluation procedure 240 and analyzing procedure 260 which utilizes sensed peripheral responses from the EMG sensors in order to determine an optimal electrode configuration and/or stimulus parameters; see, for example, paragraphs 0032 - 0036).

With respect to claims 43, 55, and 62, Examiner considers Gliner et al. to disclose several embodiments which stimulate electrode pairs, wherein an electrode pair includes **immediately adjacent electrodes** (see, for example, Figures 4C, 4D, 4E). In the alternative, Gliner et al. explicitly teaches that the analyzing procedure 360 can select any configuration of therapy electrodes in the MxN electrode array such that any combination of electrodes can be active electrodes (see last sentence of paragraph 0046). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify Gliner et al.'s selected electrode configurations of

Figures 4A and 4B such that the active electrodes are immediately adjacent to each other in order to sequentially determine whether any immediately adjacent pair of electrode within the target location T provide an optimal electrode configuration. It appears that Gliner et al. would preferably test every possible electrode configuration within the target location in order to determine the absolutely optimal electrode configuration for therapy.

With respect to claims 44, 47-48, and 63, Gliner et al. discloses that a sensing procedure is performed after each iteration of the stimulation procedure that involves monitoring a location in the patient for a response to the stimulus applied in the stimulation procedure (see paragraphs 0033-0034). The controller is structured for presenting a map that matches at least one of the individual pairs of subdural electrodes respectively to at least one of the plurality of sensors (the optimization process can terminate by storing the optimized electrode configuration in the memory of the controller, displaying the optimized electrode configuration to a practitioner, or otherwise present the optimized electrode configuration for use; see paragraph 0044).

With respect to claims 45 and 59, Gliner et al. discloses that the optimization procedure may be utilized for various therapies, including restoring motor functions, treating diseases such as epilepsy, and rehabilitating impaired brain functions (see paragraph 0056). Examiner considers resectioning a portion of the cortex based on the map to encompass utilizing the determined optimal stimulation configuration to restore motor functions, treat diseases such as epilepsy, and/or rehabilitate impaired brain functions.

With respect to claims 46 and 57, Gliner et al. discloses that the electromyograph includes a second EMG sensor at a second predetermined muscle location of the patient (the electrical signals from the EMG *sensors* are automatically received and processed by the controller; see paragraph 0034).

With respect to claim 50, Gliner discloses that if the sensed response is within a desired range, the controller can automatically test the effectiveness of other electrode configurations. In testing other electrode configurations, Examiner considers the verified electrodes to necessarily be eliminated from the stimulating procedure/pattern.

With respect to claims 51 and 61, Gliner et al. discloses an activation threshold determination procedure (see, for example, paragraphs 0058-0059).

With respect to claims 52 and 55, controller 130 necessarily includes a memory and a processor for executing computer readable program code, which enables the controller to perform the above-described operations.

With respect to claims 54, Gliner et al. discloses that the optimization process can terminate by storing the optimized electrode configuration in the memory of the controller, displaying the optimized electrode configuration to a practitioner, or otherwise present the optimized electrode configuration for use; see paragraph 0044.

With respect to claim 56, the stimulating procedure performed in Gliner et al. utilizes at least one algorithm for establishing a confidence of the event detection (stimulating procedure 220 involves several iterations performed by the controller in which the configuration of the electrodes and/or the stimulus parameters can be changed at each iteration; see paragraph 0032. Based upon the pattern of responses,

the analyzing routine 260 incrementally changes one of the stimulus parameters; see for example paragraph 0036).

With respect to claim 58, Gliner et al. discloses that the optimization method can be utilized to compensate for shifts in the target location (see, for example, paragraph 0040). Examiner considers "determining at least one dimensional offset [from a predetermined map]" to encompass utilizing the optimization method disclosed in Gliner et al. to compensate for shifts in the target location.

With respect to claim 64, Gliner et al. discloses that the controller is structured for causing the cortical stimulator to in a stimulation pattern which includes a sequence of individual stimulation passes, each stimulation pass including a sequence of applying stimuli to the individual pairs, the sequence of applying stimuli including pairing individual ones of the plurality of subdural electrodes according to a predetermined pairing pattern (stimulating procedure 220 involves several iterations performed by the controller in which the configuration of the electrodes and/or the stimulus parameters can be changed at each iteration; see paragraph 0032. Gliner et al. discloses various stimulation patterns in paragraphs 0046 with reference to Figures 4A-4C). The stimulation procedure may be based on a stimulation minimization algorithm (see, for example, paragraph 0058 which discloses that the optimization procedure seeks to select stimulus parameters that produce the desired neural activity at the lowest level of stimulation). Gliner discloses that if the sensed response is within a desired range (which Examiner considers to be verification of prior mapping data), the controller can automatically test the effectiveness of other electrode configurations. In testing other

electrode configurations, Examiner considers “the verified electrodes” to necessarily be eliminated from the stimulating procedure/pattern.

Claim Rejections - 35 USC § 103

5. Claims 49, 53, 60, and 67-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2004/0158298 (“Gliner et al.”).

As described above, Gliner et al. discloses a system and method for automatically optimizing stimulus parameters and/or electrode configurations for an implanted electrode array. The system utilizes a sensing deice 180, such as an EMG device, for determining a response in the patient to a stimulus applied to the electrode array (see paragraphs 0026, 0033-0034).

With respect to claim 49, Gliner et al. discloses that the controller 130 analyzes the responses from stimulating procedures 220 to determine a pattern of effectiveness of the corresponding stimulus configurations; see paragraph 0036. Further, Gliner et al. discloses an activation threshold determination procedure; see paragraphs 0058-0059. Examiner considers patient profile data including procedural and/or physiological information to encompass the creation of the pattern effectiveness described in Gliner et al. However, although the stimulus unit 120 contains a computer display (see paragraph 0024), Gliner et al. fails to explicitly disclose that such patient profile information may be displayed. It would have been obvious to one having ordinary skill in the art at the time of applicant’s invention to utilize the display of Gliner et al. to display such patient profile information during the stimulating procedure in order to

provide the practitioner with the detected information (i.e., the detected pattern of effectiveness and the detected activation threshold).

With respect to claim 53, Gliner et al. fails to specifically disclose locking out the stimulating step for a period where the patient's brain recovers from prior stimulation. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the computer system of Gliner et al. to incorporate a locking out time period since it is known in the art that application of too much electrical stimulus within a particular time period may be harmful to the patient.

With respect to claim 60, Gliner et al. discloses that a sensing procedure is performed after each iteration of the stimulation procedure that involves monitoring a location in the patient for a response to the stimulus applied in the stimulation procedure (see paragraphs 0033-0034). The controller is structured for presenting a map that matches at least one of the individual pairs of subdural electrodes respectively to at least one of the plurality of sensors (the optimization process can terminate by storing the optimized electrode configuration in the memory of the controller, displaying the optimized electrode configuration to a practitioner, or otherwise present the optimized electrode configuration for use; see paragraph 0044). Gliner et al. fails to specifically disclose that displaying the optimized electrode configuration to a practitioner may include displaying a relationship between the data set of EMG measurements and a scaled graphical image or a stored map profile of a cortex. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the display of Gliner et al. to display a relationship between the data set of EMG

measurements and a scaled graphical image or a stored map profile of a cortex in order to provide the practitioner with a visual representation of the relationship between the selected electrode configuration and the corresponding stimulation site on the cortex.

With respect to claim 67, as previously described, the controller is structured for presenting a map that matches at least one of the individual pairs of subdural electrodes respectively to at least one of the plurality of sensors (the optimization process can terminate by storing the optimized electrode configuration in the memory of the controller, displaying the optimized electrode configuration to a practitioner, or otherwise present the optimized electrode configuration for use; see paragraph 0044). Gliner et al. fails to specifically disclose that displaying the optimized electrode configuration to a practitioner may include graphically presenting correlation between the detected muscle contraction and a particular individual pair. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the display of Gliner et al. to display such a graphical representation in order to provide the practitioner with a visual representation of the relationship between the selected electrode configuration and the corresponding stimulation site on the cortex.

With respect to claim 68, Gliner et al. fails to specifically disclose that the controller utilizes a clock for matching a stimulation signal at one of the individual electrode pairs with a single EMG detection event. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the computer system of Gliner et al. to utilize a common clock to control both stimulation and detection since it is known in the art that such timing information can be useful in

associating two events such as the application of stimulus and the detection of a response event.

Response to Arguments

6. Applicant's arguments filed 4/26/06 have been fully considered but they are not persuasive.

7. With respect to claims 43, 52, 55, and 62, Applicant argues that Gliner et al. fails to teach sequentially stimulating individual pairs consisting of immediately adjacent electrodes. Gliner et al. discloses that the stimulating procedure 220 involves several iterations performed by the controller in which the configuration of the electrodes and/or the stimulus parameters can be changed at each iteration; see paragraph 0032. Each of the electrodes in the grid can be independently coupled to the pulse system so that individual electrodes can be activated or inactivated as desired (see paragraph 0045). Gliner et al. discloses various stimulation patterns in paragraphs 0046 with reference to Figures 4A-4C, including stimulating individual pairs of immediately adjacent electrodes of the grid as illustrated at Fig. 4C, 4D, and 4E.

In the alternative, Examiner has provided an alternative 103 rejection of the relevant claims above. Gliner et al. explicitly teaches that the analyzing procedure 360 can select any configuration of therapy electrodes in the MxN electrode array such that any combination of electrodes can be active electrodes (see last sentence of paragraph 0046). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify Gliner et al.'s selected electrode configurations of

Figures 4A and 4B such that the active electrodes are immediately adjacent to each other in order to sequentially determine whether any immediately adjacent pair of electrode within the target location T provide an optimal electrode configuration. It appears that Gliner et al. would preferably test every possible electrode configuration within the target location in order to determine the absolutely optimal electrode configuration for therapy.

Further, with respect to claim 52 that recites "any two adjacent ones of the plurality of electrodes being a pair," Examiner notes that the broadest reasonable interpretation of "adjacent" is close but not necessarily touching. Examiner considers the active electrodes of Figures 4A and 4B in Gliner et al. to be a pair of adjacent electrodes.

8. With respect to claims 65 and 66, Applicant argues that Gliner et al. does not teach any method relating to mapping discrete locations of a cortex to associated detections for muscle contractions. However, as described in the above rejection, Examiner considers the optimization procedure described in Gliner et al. to teach the claimed recitations of cortical mapping. The controller of Gliner et al. detects EMG events in response to the applied stimulus (controller 130 receives signals corresponding to the magnitude of the responses from the sensing device 180 as described in paragraph 0027) and associates the detected reaction with one of the individual pairs of the plurality of subdural electrodes (the controller performs an evaluation procedure 240 and analyzing procedure 260 which utilizes sensed peripheral responses from EMG sensors in order to determine an optimal electrode configuration

and/or stimulus parameters; see, for example, paragraphs 0032 - 0036). Examiner considers "producing a map identifying at least one specific functional location of the cortex" and "utilizing the detected EMG events to map the cortex" to encompass this associating step disclosed in Gliner et al. because Gliner et al. necessarily establishes a functional relationship between the applied stimulus location and the detected EMG event.

Conclusion

9. Applicant's amendment (i.e., filing of all new claims) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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6/7/06

George Manuel
Primary Examiner